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| 10/718,504 | 11/19/2003 | Gordon H. Epstein | 021872-001010US | 8230 |
| 20350 7590 01/31/2011 KILPATRICK TOWNSEND & STOCKTON LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834 | | | | |
| EXAMINER | | | | |
| RYCKMAN, MELISSA K | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/718,504

Applicant(s)

EPSTEIN ET AL.

Examiner

MELISSA RYCKMAN

Art Unit

3773

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19, 21-26 and 28-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19, 21-26 and 28-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-945)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This office action is in response to claims and arguments filed 7/2/10.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19, 21-26, and 28-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The originally filed application does not disclose the first deformable membrane being "non-permeable".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 19, 22-26 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keegan et al. (U.S. Pub. No. 2003/0187474 A1) and further in view of McGuckin, Jr. et al. (U.S. Patent No. 7,331,976).

Keegan teaches an expansible device for use in a tissue tract extending from a skin surface to a blood vessel, the device comprising:

- a tubular member (catheter used to deliver the balloon, para. 488) having a lumen, a proximal end, and a distal end
- a first expansible member (26, Fig. 5) disposed on the distal end of the tubular member (when catheter is placing the balloon stent, the first expansible member is on the distal end of the tubular member), the first expansible member having a contracted configuration and an expanded configuration, wherein the first expansible member consists essentially of a single wire (26, para. 489, the hook 26 of the support frame, this means that element 26 is part of the support frame) that can be retracted into the lumen of the tubular member (capable of being retracted into lumen of the balloon stent catheter) to shift the single wire from a helical expanded configuration to a straightened contracted configuration
- a first deformable membrane at least partially disposed over the first expansible member in the expanded configuration (20, Fig. 5, the membrane in non-permeable to large emboli in the blood vessel)
- a second expansible member (balloon, Fig. 6) disposed proximal to the first expansible member and on the distal end of the tubular member, the second expansible member having a contracted configuration and an expanded configuration comprising an elongate cylinder having a length

sufficient to extend through at least a portion of the tissue tract from the blood vessel to the skin surface (Fig. 6)

- a predetermined volume of air contained within the tubular member (catheter that delivers balloon stent) inflates the second expansible member (para. 488).
- the second expansible member has a length in a range from about 0.1 inch to about 2.0 inches (Fig. 5)
- the first and second expansible members are deployed sequentially (Fig. 5-6)

Keegan teaches the claimed invention but does not have the first deformable membrane having a spherical shape when the first expansible member is in the expanded configuration, or the second expansible member comprises a coil or spring of wire with a membrane. However, McGuckin teaches:

- wherein the first deformable membrane has a spherical shape when the first expansible member is in the expanded configuration (Fig. 6, element 50)
- the second expansible member (34) comprises a coil or spring of wire (34) with the diameter as defined in the claims (col. 7, ll. 55-67).
- a second deformable membrane (membrane around 34) at least partially disposed over the second expansible member in the expanded configuration (fig. 6)
- ribs on a surface of the second deformable membrane (Fig. 6)

- a reference stop (40) disposed between the first deformable membrane and the distal end of the tubular member (Fig. 6)

It would have been obvious to one of ordinary skill in the art to use the shape of McGuckin with the device of Keegan as the spherical shape may be preferable in different applications, as the front face would be rounded instead of flat, making the entry of the device into a certain body part smoother. The sphere of McGuckin is structurally strong also, because the stress concentration is evenly distributed in a sphere.

Regarding Claims 22 and 24, it would have been obvious to one of ordinary skill in the art to use the second expansible member of McGuckin, as using the struts (element 60) and membrane of McGuckin in exchange for the balloon of Keegan is well known in the art in performing as equally well as a balloon in anchoring the device.

Regarding Claim 23, McGuckin teaches a device for occluding an opening, wherein the second expansible member is a diameter of .19 inches. It would have been an obvious matter of design choice to disclose the diameter of the coil and wire as being within the disclosed range since it appears that the device of Latson performs the task of closing a hole in tissue equally well as that of the disclosed application, and it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Regarding claim 28, McGuckin teaches a stop between the first deformable member and the distal end of the tubular member, it would have been obvious to one of

ordinary skill in the art to use the stop of McGuckin with the device of Keegan as this aides in delivery of the device and expansion and retraction of the device.

Claims 29-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keegan et al. (U.S. Pub. No. 2003/0187474 A1) and McGuckin, Jr. et al. (U.S. Patent No. 7,331,976), and further in view of Brenneman et al. (US 6071300).

Keegan and McGuckin teach the claimed invention as described in the above rejection, including the first expansible member disposed on a distal end of the tubular member (via element 10 of Keegan), but do not teach the specified locations of the first and second expansible members, however Brenneman teaches the first expansible member is deployed against a blood vessel wall (fig. 1) and the second expansible member is deployed against a tissue tract (fig. 1).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the device of Keegan and McGuckin in the location as taught by Brenneman, as this is shown to be well-known and effective in the art.

The combination of Keegan and McGuckin teach the claimed invention, and further teaches wherein the first and second expansible members are deployed sequentially, but fails to teach wherein the first and second expansible members are deployed simultaneously. It would have been an obvious matter of design choice, as necessary, to modify the method of Keegan and McGuckin by simultaneously deploying the first and second expansible members, since the combination of Keegan and McGuckin is capable of performing that function, and in paragraph 79 of the present

application, applicant asserts that it is preferable to deploy the first and second members sequentially, and it appears that a method with the combination of Keegan and McGuckin would perform the task of sealing a puncture equally well as that of the present application.

Response to Arguments

Applicant's arguments filed 7/2/10 have been fully considered but they are not persuasive. The applicant argues:

- Keegan does not teach the first deformable membrane being "non-permeable"

The examiner's position is there is no support in the originally filed application for "non-permeable" the applicant points to paragraphs 70 and 77 of the application. The examiner does not find support for "non-permeable" in these paragraphs. Paragraph 70 of the current application discusses a "continuous barrier over the expansible member 302, particularly on an outer surface in contact with the puncture site" this simply means a barrier to a certain object, this does not necessary mean it is "non-permeable". Keegan teaches the membrane is non-permeable to embolic material.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA RYCKMAN whose telephone number is (571)272-9969. The examiner can normally be reached on a flexible schedule, email address is melissa.ryckman@uspto.gov.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571)-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MKR
/Melissa Ryckman/
Examiner, Art Unit 3773

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773